

REMARKS

I. General

Applicants respectfully request reconsideration of the present application.

II. Disposition of the Claims

Claims 1-3, 5-24, and 28-50 were previously cancelled, without prejudice or disclaimer.

Claims 4 and 25-27 were previously presented and examined.

III. Claim Rejections – 35 U.S.C. § 102

Claims 4 and 25-27 are rejected under 35 U.S.C. § 102(a) as being anticipated by WO 98/11884. Office action, p. 2. The Examiner directed Applicants to the disclosure at pp. 12-13, concerning, e.g., a medicament for combination therapy of “NIDDM patients to improve their weight and diabetic control comprising a compound of formula I and an insulin sensitizing agent.” It is believed that the remainder of WO 98/11884 relates to “a method of reducing insulin resistance in humans in whom Impaired Glucose Tolerance (IGT) and Non-Insulin Dependent Diabetes Mellitus (NIDDM) have not presented.” WO 98/11884, p. 1, ll. 3-5.

A reference cannot anticipate what it fails to describe. More specifically, here, picking and choosing from various compounds of formula I and insulin sensitizers is required to reach an embodiment with the scope of the present claims. As such, WO 98/11884 does not anticipate the present claims.

Moreover, during prosecution of this application’s parent application no. 09/380,059, now U.S. Pat. No. 6,329,403, Applicants filed an amendment dated February 23, 2001, requesting the addition of claims directed to the same subject matter as that now claimed in the present application, i.e., “a method for lowering the concentration of glycosylated hemoglobin.”

However, Examiner R. Cook withdrew those claims from consideration in an Office action dated April 23, 2001, because they were “directed to an invention that is independent or distinct from the invention originally claimed,” i.e., a method of treating diabetes, diabetic complications, or IGT. April 23, 2001, Office action, p. 2 (submitted for consideration). This clearly indicates that Examiner R. Cook considered the subject matter of the present invention to be patentably distinct from that subject matter of the parent application: “a method for treating diabetes, diabetic complications or impaired glucose tolerance”—the same subject matter as WO 98/11884. In other words, the PTO has held that the present subject matter is not the same as (35 U.S.C. § 102) or obvious (35 U.S.C. § 103) in view of treating diabetics, diabetic complications and IGT. The present Examiner cannot take a contrary position. Thus, the rejection should be withdrawn.

IV. Claim Rejections – 35 U.S.C. § 103

1. Declaration of Dr. Odaka

The Examiner requested clarification of the data presented in the Declaration of Dr. Odaka, specifically the results shown in Table 1. Office action, p. 4. The Declaration states on page 2, lines 2 to 3 from the bottom, “Changes in HbA1c level, plasma glucose and plasma triglyceride are shown in Table 1.” The “–” sign in front of the numerical values means “decrease” of the change in values (final less initial), such as the HbA1c level, the plasma glucose, and the plasma triglyceride. The unit for HbA1c level is “%” as shown also in Tables 2 and 3 of the cited Grossman et al., pp. 1032-33. The Declaration thus clearly demonstrates unexpected results of the present invention. Firstly, Dr. Odaka testified that pioglitazone hydrochloride in combination with sibutramine provided unexpectedly superior effects of lowering HbA1c (%), plasma glucose, and plasma triglyceride. Odaka Dec., p. 2, Table 1. Secondly, the same combination “provided an effect of inhibiting body weight increase.” Odaka Dec. p. 2, Table 2. Dr. Odaka testified that these results were unexpected. Odaka Dec., p. 2. These facts, and others of record, show that the rejection should be withdrawn.

2. Rejection of claims 4 and 25-27

Claims 4 and 25-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Grossman et al. and Hauner in view of WO 93/03724. Office action, p. 4. The Examiner agrees that Grossman fails to teach the presently recited combination. Office action, p. 5. The Examiner also stated that “the addition of an ananoretic [like sibutramine] is not essential for lowering of glycosylated hemoglobin.” Office action, p. 6. It is believed that this statement is an agreement that the addition of ananoretic like sibutramine would not have been expected to provide unexpected effects. However, Table 4 in Grossman et al. at page 1034 shows at most 35.4% $[=100\% \times (0.65 - 0.48) / 0.48]$ reduction in HbA1c level by the “combination of pioglitazone and SU” (Study 2) as compared with “pioglitazone” (Study 1). In contrast, Table 1 in the Declaration of Dr. Odaka shows as much as 300% $[=100\% \times (1.2 - 0.3) / 0.3]$ reduction in HbA1c level by the “combination of pioglitazone and sibutramine” (Group D) as compared with “pioglitazone” (Group B). Thus, the present invention shows 847% $[=100\% \times (300 / 35.4)]$ greater reduction effects of HbA1c than Grossman et al. Such excellent effects provided by the “combination of pioglitazone and sibutramine” is unobvious over any of Grossman et al., Hauner, WO 93/03724, and their combination. Therefore, the present invention is unobvious over any of Grossman et al., Hauner, WO 93/03724, and their combination.

Further, although the Examiner stated that WO 93/03724 describes use of compositions for the same purpose as the present invention, Office action, p. 5, the purpose of WO 93/03724 and that of the present invention should not be considered the same. As noted above, due to the restriction requirement in the parent application, the present Examiner must consider the present claimed subject matter to be patentably distinct from that subject matter of the parent application, i.e., “a method for treating diabetes, diabetic complications or impaired glucose tolerance.”

Thus, the rejection should be withdrawn.

CONCLUSION

It is believed that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.


The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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Attachment: April 23, 2001, Office action, p. 2

ATTACHMENT CITED ON PAGE 3 OF AMENDMENT
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Newly submitted and amended claims 2-7, 11, 24-31, 44-47, are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they are to a method for lowering the concentration of glycosylated hemoglobin and treating obesity.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 2-7, 11, 24-31, 44-47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 15-17, 22-23, 32-43, 48-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 15-17, 22-23 the recitations "or their salts" is confusing as to whether all salts are required. Amending it to recite "or a salt thereof" will overcome this rejection.

The claims 48-49 depend, in part, from withdrawn claims. Amending them to delete reference to said withdrawn claims will overcome this rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-17, 22-23, 32-43, 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 749 751 in view of WO 03/03724 (page 5, among others), WO 97/27847